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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|-----------------------------|-------------------|
| 09/881,322 | 06/14/2001 | Frank Robert Busch | PC10734A US | 7157 |
| 7590 | 08/13/2002 | | | |
| Gregg C. Benson Pfizer Inc. Patent Department, MS 4159 Eastern Point Road Groton, CT 06340 | | | EXAMINER HUI, SAN MING R | |
| | | | ART UNIT 1617 | PAPER NUMBER 6 |
| | | | DATE MAILED: 08/13/2002 | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|------------------------|---------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 09/881,322 | BUSCH ET AL. |
| | Examiner | Art Unit |
| | San-ming Hui | 1617 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-61 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) _____ is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) 1-61 are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All
 - b) Some *
 - c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ . | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-17, drawn to a method of treating systemic lupus erythematosus employing growth hormone secretagogue (GHS), classified in class 514, subclass 215, 230.5, 226.5, 248, 249, 250, 252.04, 252.06, 252.12, 256, 257, 258, and 290-314.
- II. Claims 18-29 and 31, drawn to a pharmaceutical composition and a kit containing GHS and a secondary agent selected from methotrexate, dapsone, a glucocorticoid or an antimalarial, classified in class 514, subclass 177, 178, 171, 215, 230.5, 226.5, 248, 249, 250, 252.02, 252.04, 252.06, 252.12, 256, 257, 258, and 290-314; class 424, subclass 400+.
- III. Claims 30, drawn to a method of treating systemic lupus erythematosus employing growth hormone secretagogue (GHS) and a secondary agent selected from methotrexate, dapsone, a glucocorticoid or an antimalarial, classified in class 514, subclass 177, 178, 171, 215, 230.5, 226.5, 248, 249, 250, 252.02, 252.04, 252.06, 252.12, 256, 257, 258, and 290-314.
- IV. Claims 32-47, drawn to a method of treating inflammatory bowel disease employing GHS, classified in class 514, subclass 215, 230.5, 226.5, 248, 249, 250, 252.04, 252.06, 252.12, 256, 257, 258, and 290-314.

- V. Claims 48-57, and 61, drawn to a pharmaceutical composition and a kit containing GHS and a secondary agent selected from prednisone, sulfasalazine, mesalamine and olsalazine, classified in class 514, subclass 177, 178, 171, 215, 230.5, 226.5, 248, 249, 250, 252.02, 252.04, 252.06, 252.12, 256, 257, 258, 290-314, 353, and 570; class 424, subclass 400+.
- VI. Claims 58-60, drawn to a method of treating inflammatory bowel disease employing GHS and a secondary agent selected from prednisone, sulfasalazine, mesalamine and olsalazine, classified in class 514, subclass 177, 178, 171, 215, 230.5, 226.5, 248, 249, 250, 252.02, 252.04, 252.06, 252.12, 256, 257, 258, 290-314, 353, and 570.

The inventions are distinct, each from the other because of the following reasons:

Inventions I, III and IV, VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. For example, the invention of I and III function to treat systemic lupus erythematosus; while the inventions of Group IV and VI function to treat inflammatory bowel disease.

Inventions II and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation. The

invention of Group II employs two agents: a GHS and a secondary agent selected from methotrexate, dapsonc, a glucocorticoid or an antimalarial. The inventions of Group V employs two agents which are different from that of invention II: a GHS and a secondary agent selected from prednisone, sulfasalazine, mesalamine and olsalazine. Thus, the invention of Groups II and V operate by the administration of a distinct set of active agents.

Inventions II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the method of treating systemic lupus erythematosus can be practiced with a materially different product such as NSAIDs.

Inventions V and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the method of treating inflammatory bowel disease can be practiced with a materially different product such as cyclosporine and azathioprine.

Inventions I and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of

operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation. For example, the invention of group I operates by employing one agents and the invention of group III operates by employing two agents.

Inventions IV and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation. For example, the invention of group IV operates by employing one agents and the invention of group VI operates by employing two agents.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Election of Species

Claims 1-7, 14-21, 28-38, 45-51, and 58-61 are generic to a plurality of disclosed patentably distinct species comprising a GHS of Formula I.

The GHS compound of Formula I can be classified into various classifications depending on the heterocyclic moieties the compounds have. For example, if the GHS compound of Formula I has a seven-member ring with one nitrogen moiety, it is classified in class 514, subclass 215; if the GHS compound of Formula I has a six-member heterocyclic system with nitrogen and oxygen, it is classified in class 514,

subclass 262.5 or 230.5; if the GHS compound of Formula I has a six-member heterocyclic system with a 1,2-diazole moiety, it is classified in class 514, subclass 248, 249, or 250; if the GHS compound of Formula I has a six-member heterocyclic system with a 1,4-diazole moiety, it is classified in class 514, subclass 252.04, 252.06, or 252.12.

Due to the structural dissimilarities of active GHS compounds encompassed by the claims and their corresponding diversity in classification, the search for all species presents an undue burden on the office.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed GHS compound, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Because the above restriction/election requirement is complex, a telephone call to applicant's agent to request an oral election was not made. See M.P.E.P. Sec. 812.01.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention and a single disclosed GHS compound to be examined even though the requirement be traversed (37 CFR 1.143).

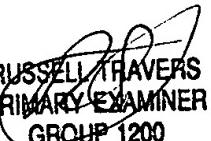
Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (703) 305-1002. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Russell Travers, J.D., can be reached on (703) 308-4603. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

San-ming Hui
August 9, 2002


RUSSELL TRAVERS
PRIMARY EXAMINER
GROUP 1200